STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH
ADVERSE EVENT REPORTING FORM

An **Adverse Event** means a discrete, auditable and clearly defined occurrence with a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable.*
Serious describes an event that results in death or loss of a body part, disability or loss of bodily function lasting more than seven days or still present at the time of discharge from an inpatient facility.*
Disability means a physical or mental impairment that substantially limits one or more of the major life activities of an individual.*
(* as defined by the National Quality Forum, 2002)

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
1. SURGICAL EVENTS		

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☐ 1A. Surgery performed on the wrong body part	Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent**.** Surgery includes endoscopies and other invasive procedures.	**Surgery is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or the procedure is carried out using an instrument that is introduced through a natural body orifice. Surgeries include a range of procedures from minimally invasive dermatological procedures (biopsies, excision and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. It includes minimally invasive procedures involving body cavity through a needle or trocar. It does not include use of such things as use of otoscopes and drawing blood.** **Organizations may choose to adopt a list of surgical procedures to supplement the definition above; on example of such a list in common use is that of the Institute of Clinical Systems Improvement.** **Surgery begins, regardless of the setting at point of surgical incision, tissue puncture, or insertion of instrument into tissues, cavities, or organs.** **Surgery ends after counts have concluded and the surgical incision has been closed and/or operative device(s) such as probes have been removed, regardless of setting. (e.g., post anesthesia recovery unit, surgical suite, endoscopy unit)** This event **is intended to capture** instances of: • Surgery on the right body part but on the wrong location on the body; e.g. left/right (appendages/organs_, level (spine) • Wrong site surgery, corrected intra-operatively, is still a wrong site procedure if the surgery had begun, based on the definition above. The event **is not intended** to capture: • Changes in plan upon surgical entry into the patient with discovery of pathology in close proximity to the intended

		place where risk of a second surgery outweighs benefit of patient consultation, or unusual physical configuration
☐ 1B. Surgery performed on the wrong patient	Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient. Surgery includes endoscopies and other invasive procedures.	This **is intended to capture**: • Surgical procedures (whether or not completed) initiated on one patient intended for a different patient Surgery is defined …see 1A Surgery begins…. See 1A Surgery ends….See 1A
☐ 1C. Wrong surgical procedure performed on a patient	Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. Surgery includes endoscopies and other invasive procedures.	This event **is intended to capture**: • Insertion of the wrong medical implant into the correct surgical site This event is **not intended to capture**: • Changes in plan upon surgical entry into the patient with discovery of pathology in close proximity to the intended place where risk of a second surgery outweigh benefit of patient consultation, or unusual physical configuration.
☐ 1D. Unintended retention of a foreign object in a patient after surgery or other procedure	Excludes a) objects intentionally implanted as part of a planned intervention; b) objects present prior to surgery that were intentionally retained; and c) objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention (such as micro-needles, broken screws).	This **is intended to capture**: • Occurrences of unintended retention of objects at any point after the surgery ends regardless of setting (post anesthesia recovery unit, surgical suite) and regardless of whether the object is to be removed.

☐ 1E. Intraoperative or immediate post-operative death in an ASA (American Society of Anesthesiology) Class I patient	Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately post-operative means within 24 hours after surgery, or other invasive procedure was completed, or after administration of anesthesia (if surgery was not completed).	This **is intended to capture**: • ASA Class I patient death associated with administration of anesthesia whether or not the planned surgical procedure was carried out.
2. PRODUCT OR DEVICE EVENTS		
☐ 2A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	Includes generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.	The term **"detectable" is intended to capture** contaminations that can be seen with the naked eye or with use of detection mechanisms in general use; these contaminations are to be reported at such time as they become known to the provider or healthcare facility. (Detection mechanisms may include such things as cultures and tests that signal changes in pH or glucose levels.)

☐ 2B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended	Includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators.	This event **is intended to capture** occurrences whether or not the use is intended or described by the device manufacturers' literature. The U.S. Food and Drug Administration (FDA) defines medical device as: • Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, • Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or • Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."
☐ 2C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.	High-risk procedures, other than neurosurgical procedures, that include a small, but known risk of air embolism reportable under this event include, but are not limited to procedures involving the head and neck, vaginal delivery and caesarean section, spinal instrumentation procedures and liver transplantation
3. PATIENT PROTECTION EVENTS		
☐ 3A. Infant discharged to the wrong person		Stedman's Online Medical Dictionary defines an infant as a child under the age of 1 year.

☐ 3B. Patient death or serious disability associated with patient elopement (disappearance).	Excludes events involving competent adults.	The term **"competent" adult should be interpreted** in accordance with prevailing legal standards. This is **not intended to capture** death or serious disability that occurs (after the patient is located) due to circumstances unrelated to the elopement.
☐ 3C. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility	Defined as events that result from patient actions after admission to a healthcare facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility.	This event is **not intended to capture** patient suicide or attempted suicide when the patient is not physically present in the "healthcare facility".
4. CARE MANAGEMENT EVENTS		
☐ 4A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)	Excludes reasonable differences in clinical judgment on drug selection and dose. Includes administration of a medication to which a patient has a known allergy and drug-drug interactions for which there is known potential for death or serious disability	This event **is intended to capture**: • The most serious medication errors including occurrences in which a patient, known to have serious allergies to specific medications/agents, receives those medications/agents, resulting in serious harm or death. These events may occur as a result of failure to collect information about allergies, failure to review allergy information available in information systems, failure of the organization to assure availability of allergy information and prominently display such information within information systems, or other system failures that are determined through investigation to be cause of the adverse event. • Occurrences in which a patient dies or suffers serous disability as a result of failure to administer a prescribed medication. • Occurrences in which a patient dies or suffers serous disability as a result of wrong administration technique.

		This event is **not intended to capture:** • Patient death or serious disability associated with allergies that could not reasonable have been known or discerned in advance of the event. • <u>All</u> situations in which two or more medications are administered for which there are drug-drug interactions with known potential for death or serious disability, only those that result in death or serious disability.
☐ 4B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products		This event is **not intended to capture**: • Patient death or disability associated with organ rejection other than those attributable to a hyper-acute hemolytic reaction. • Patient death or disability when cause is not detectable by ABO/HLA matching.
☐ 4C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	Includes events that occur within 42 days post-delivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy.	This event is **not intended to** create a new obligation; the organization's obligation is to report the event when made aware of the maternal death or serious disability either by re-admittance or by the patient's family. **Low-risk pregnancy refers to** a woman aged 18-39, with **no previous diagnosis** of essential hypertension, renal disease, collagen-vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of poor pregnancy outcome

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☐ 4D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility		Hypoglycemia is defined a blood glucose levels<60mgdL. (ICD-9, 251.0)
☐ 4E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates	Hyperbilirubinemia is defined as bilirubin levels >30mg/dl. Neonates refers to the first 28 days of life.	The organization's obligation is to report the event when made aware of the death or serious disability either by re-admittance or by the patient's family.
☐ 4F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	Excludes progression from Stage 2 to Stage 3, if Stage 2 was recognized upon admission.	
☐ 4G. Patient death or serious disability due to spinal manipulative therapy		Spinal manipulation, also known as adjustment, references procedures that stretch, mobilize or manipulate the spine, paravertebral tissues and other joints..
☐ 4H. Artificial insemination with the wrong donor sperm or wrong egg.		The organization's obligation is to report the event when made aware of the occurrence.

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5. ENVIRONMENTAL EVENTS		
☐ 5A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility	Excludes events involving planned treatments such as electric countershock.	This event **is intended to capture**: • Patient death or disability associated with unintended electric shock during the course of care or treatment This event **is not intended to capture**: • Patient death or disability associated with emergency defibrillation in ventricular fibrillation or with electroconvulsive therapies.
☐ 5B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances		
☐ 5C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility		
☐ 5D. Patient death or serious disability associated with a fall while being cared for in a healthcare facility	Includes but is not limited to fractures, head injuries, and intracranial hemorrhage.	

☐ 5E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility		The event **is intended to capture** instances where restraints are implicated in the death; e.g. lead to strangulation/entrapment, etc. Death/disability resulting from falls caused by lack of restraints would be captured under 'falls'. Restraints is currently defined by the Joint commission on Accreditation of Healthcare Organizations, the Center for Medicare and Medicaid Services and by some states. In the event none of those definitions apply to an institution, the following definition, which is intended to capture definitions from the named organizations, is offered – restraints means any method of restricting a patient's freedom of movement that is not a usual and customary part of a medical diagnostic or treatment procedure to which the patient or his or her legal representative has consented; is not indicated to treat the patient's medical condition or symptoms; is not indicated to treat the patient's medical condition or symptoms; or does not promote the patient's independent functioning.
6. CRIMINAL EVENTS		
☐ 6A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider		
☐ 6B. Abduction of a patient of any age		
☐ 6C. Sexual assault on a patient within or on the grounds of a healthcare facility		Language and definitions may vary based on state statute (e.g. Many states have existing statutes that may use the term "sexual assault" or "simple assault" or "criminal sexual conduct"); however, the principle and intent remain regardless of language required based on jurisdiction.

☐ 6D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility		Language and definitions may vary based on state statute (e.g., many states have existing statutes that use the terms "first degree assault" or "second degree assault" or "battery").
7. CONNECTICUT SPECIFIC EVENTS		
☐ 7A. Perforations during open, laparoscopic and/or endoscopic procedures resulting in death or serious disability	Includes perforations which require resection.	
☐ 7B. **DO NOT USE THIS CATEGORY**	**EVENTS FORMERLY REPORTABLE AS <u>7B</u> ARE NOW REPORTABLE AS <u>5D</u>**	
☐ 7C Obstetrical events resulting in death or serious disability to the neonate		
☐ 7D. Significant medication reactions resulting in death or serious disability	Includes medication reactions, anaphylaxis, or development of methemoglobinemia following use of anesthetic spray.	

☐ 7E Laboratory or radiologic test results not reported to the treating practitioner or reported incorrectly which result in death or serious disability due to incorrect or missed diagnosis in the emergency department.		
☐ 7F. Nosocomial infections defined as reportable sentinel events by the Joint Commission on Accreditation of Healthcare Organizations.	All identified cases of death and major permanent loss of function attributed to a nosocomial infection (i.e. except for the infection, the patient probably would not have died or suffered major permanent loss of function.)	
☐ 7G. Patient death or serious disability as a result of surgery	Excludes events reported at 1E and 7A Includes: Hemorrhage greater than 30% of circulating blood volume; **and/or** Unanticipated death or serious disability in an ASA Class 2 patient intra-operatively, or post-operatively within twenty-four hours of the surgery.	See definition of "**surgery**" at 1 A. See definition of "**death" and "serious disability**" as defined by the National Quality Forum. **Class III Hemorrhage** according to the American College of Surgeons' Advanced Trauma life Support (ATLS) is defined as loss of 30-40% of circulating blood volume. This **is intended to capture:** ASA Class 2 patient death associated with administration of anesthesia whether or not the planned surgical procedure was carried out. Please refer to the Cleveland Clinic, ASA Physical Status Classification for guidance. http://my.clevelandclinic.org/services/anesthesia/hic_asa_physical_classification_system.aspx